



Application for an operating permit for a class II establishment to carry out exposures for medical purposes using X-ray generating equipment



The undersigned hereby requests, in accordance with Articles 44 and 49 of the Law of 28 May 2019 on radiation protection, an operating permit for a class II classified establishment for the implementation of the following practices: using X-ray generating equipment to carry out exposures for medical purpose.

1. Input

Fields marked with an * are compulsory

General information on the applicant

Surname(s) and first name(s) of
the applicant*:

Capacity*:

Name of the establishment*:

Business name*:

National identification number*:

Registered office*:

Administrative office*:

Place of operation (if different):

Purpose of the application and equipment

The present application is:

☐ an **initial application** (e.g.: creation of a new building).

☐ an application for a **renewal** without modification to the operating conditions of an authorised establishment

authorisation reference number:

expiring on:

☐ an application for a **modification** of the operating conditions of an authorised establishment

authorisation reference number:

expiring on:

modifications requested:

Nature and purpose of the
establishment:

(describe the reason for the application, the
intended use of the radiation: use the
terminology used in Annex X.B of the Grand
Ducal regulation)



1. Number of medical specialists in radiology or diagnostic radiology*:

2. For each specialty, indicate the number of medical specialists authorised to perform diagnostic radiology using X-rays as their specialty*:

3. For each specialty, the number of medical specialists performing interventional radiology procedures other than those indicated under 1*:

please attach:

Two inventories with the medical radiological equipment

- **Form-List-Xray-Equipment**
- **Form-List-Ancillary-Equipment**

are to be completed and attached to the application for authorisation

Occupational exposure and exposure of the public

please attach:

A report describing:

- the prior analysis of the risk detailing:
 - the occupational exposure and
 - the exposure of the publicas foreseen under normal operating conditions as well as the applicable dose constraints.
- the protective or safety measures recommended both with regard to the devices, the equipment, the installations and with regard to the premises in which they are located;
- using the facility plan, a radiation protection calculation indicates the minimum required protection of the walls, ensuring that no person outside the radiology room can be exposed beyond the anticipated public dose limits.
- The anticipated number of persons liable to be exposed to radiation from the source in the context of their professional duties
- the radiation protection qualifications of the staff in charge of the production, distribution, use, maintenance or monitoring of the devices capable of producing ionising radiation

Radiation protection officer

This is the contact person for exchanges between the establishment and the Radiation Protection Division. This person must be technically competent in radiation protection matters related to a specific type of practice to supervise or implement radiation protection provisions. Their tasks are described in Art. 7 of the Grand Ducal regulation on radiation protection.

Surname and first name*:

Business address*:

Business phone number*:

Business email address*:

Substitute representative(s) (if applicable):

Surname and first name:



Business address:

Business phone number:

Business email address:

please attach:

- a certificate attesting to the radiation protection qualification of the person responsible for radiation protection and, where appropriate, of his or her substitute representative.

Insurance

please attach:

- a certificate (or at least a draft of a contract) of liability insurance **covering the use of ionising radiation sources or X-ray equipment.**

Map of the installations

Place of use of the equipment:

Identifier of the cadastral plot:

Commune :

Cadastral section:

please attach:

- Map of the places and installations with namely the premises where the sources of ionising radiation are used. This map must also show all premises situated within a radius of less than 20 metres from the location of the radioactive sources, as well as the purpose of these premises;

Internal response plan

please attach:

- Excerpts from the internal response plan for dealing with different types of radiological emergencies

Name of the external consultant expert in radiation protection (ERP; for the radiation protection aspects of the public and workers) and name and contact details of the expert in medical physics (EPM)

Surname and first name of the ERP*:

Surname and first name of the EPM*:

Business address* :

Business phone number*:

Business email address*:



Proof of compliance with European regulations on medical devices

please attach (for each device covered by the application):

- EC marking: **declaration of conformity and certificate of the notified body** ;
- Indication of the manufacturer and the single European representative, where appropriate indication of the other relevant economic operator (importer or distributor) responsible for placing the product on the European market as well as the contact person responsible for ensuring compliance with the regulations and for vigilance;

Fee

The undersigned has taken note that by the deadline of 1 June of the year, any establishment in Class II is required to pay a fee of EUR 500.

Proof of payment must be sent to the National Health Directorate (Direction de la santé).

2. Signature

By signing the document, the applicant certifies that the information provided is correct

Done at*:

Date*:

Head of the establishment

Surname and first name(s)*:

Signature*:

Radiation protection officer

Surname and first name(s)*:

Signature*: